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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,462	01/20/2006	Stephen Mark McAllister	PU60404	9920

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/565,462	MCALLISTER ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/20/06;10/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 7-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 26-28, 108-110 and 118-120 of copending Application No. 10/060603 ('603). Although the conflicting claims are not identical, they are not patentably distinct from each other because copending application '603 teaches a capsule comprising a shell composed of an extruded and injection molded capsule shell composition material comprising aminoalkyl Methacrylate Copolymer E present in an amount of 30 to 90%, a lubricant from 0 to about 30% w/w, at least one dissolution modifying excipient present in an amount from about 5 to 70% w/w selected from the group consisting of a swellable

solid, a disintegrant, a non-reducing sugar, and a water soluble filler, or a combination or mixture thereof, and optionally a plasticizer from about 0 to 5% w/w and/or a processing agent from about 0 to about 10%. Stearyl alcohol as a lubricant is found in claims 3-6. Dissolution modifying agent includes hydroxypropyl cellulose (HPC) (see claims 7, 8, 108 and 118).

The '603 copending application does not teach mixture of two HPC as a dissolution modifying excipient.

Nishioka teaches combination of HPC with different viscosity levels to obtain any release profile desired (column 2, lines 25-50).

Gidwani teaches a sustained release composition comprising combination of HPC having different MW (column 3, lines 51-61; and example 4). Gidwani further teaches the ratio between the at least two HPC with different MW is from about 1:6 to 6:1 (column 4, lines 1-7).

Li teaches an oral extended release composition comprising mixture of at least two HPC having different MW (column 10, lines 47-59; Tables 8-10; and claims).

Thus, it would have been obvious to one of ordinary skill in the art to optimize the capsule shell of the present invention to include a mixture of at least two HPC in view of the teachings of Nishioka, or Gidwani, or Li, because Nishioka teaches that selecting and combining at least two HPC of different viscosity levels, release profile of a dosage form can be adjusted; because Gidwani teaches that mixture of at least two HPC to obtain a sustained release profile is known in the art; because Li teaches that combining same polymers with different viscosity (V_1 and V_2), the release rate of the drug from the

dosage form can be modified by adjusting the ratio of the polymers (column 8, lines 32-36); because McAllister teaches that two or more polymers may be used in combination to form blends having the desired drug release profile (page 25, lines 24-26).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims contain the trademark/trade name "Eudragit 4135F" or "Klucel". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade

name is used to identify/describe the polymers blend for the capsule shell and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAllister et al. US 2003/0049311, in view of Nishioka et al. US 5,861,173 or Gidwani et al. US 6,270,797 or Li et al. US 7,476,403.

McAllister teaches a capsule comprising a shell composed of an extruded and injection molded capsule shell composition material comprising Eudragit 4135F present in an amount of 30 to 90%, a lubricant from 0 to about 30% w/w, at least one dissolution modifying excipient present in an amount from about 5 to 70% w/w selected from the group consisting of a swellable solid, a disintegrant, a non-reducing sugar, and a water soluble filler, or a combination or mixture thereof, and optionally a plasticizer from about 0 to 5% w/w and/or a processing agent from about 0 to about 10% (abstract; paragraphs 0124-0136; and claims). The composition further comprises surfactant, plasticizer, and processing aid (paragraphs 0141-0145 and 0153-0154). Dissolution modifying agents include hydroxypropyl cellulose (HPC) are disclosed in paragraphs 0146-0151. McAllister further teaches the use of lubricant such as stearyl alcohol in an

amount of from about 0 to about 30% (paragraph 0155-0156). The composition further comprises hydrophilic excipient such as HPC (paragraphs 0195-0197).

McAllister does not explicitly teach mixture of at least two HPC having different MW. However, such combination is known in the art. See for example:

Nishioka at column 2, lines 25-50, for the teachings of combining HPC of different viscosity levels to obtain any release profile desired;

Gidwani teaches a sustained release composition comprising combination of HPC having different MW (column 3, lines 51-61; and example 4). Gidwani further teaches the ratio between the at least two HPC with different MW is from about 1:6 to 6:1 (column 4, lines 1-7); and

Li teaches an oral extended release composition comprising mixture of at least two HPC having different MW (column 10, lines 47-59; Tables 8-10; and claims).

Thus, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to optimize the injection molding composition of McAllister to include mixture of at least two HPC in view of the teachings of Nishioka, or Gidwani, or Li to obtain the claimed invention. This is because Nishioka teaches that selecting and combining at least two HPC of different viscosity levels, release profile of a dosage form can be adjusted; because Gidwani teaches that mixture of at least two HPC to obtain a sustained release profile is known in the art; because Li teaches that combining same polymers with different viscosity (V_1 and V_2), the release rate of the drug from the dosage form can be modified by adjusting the ratio of the polymers (column 8, lines 32-36); because McAllister teaches that two or more polymers may be used in combination

to form blends having the desired drug release profile (paragraph 0183), and because McAllister teaches the desirability for combining at least two dissolution (release) modifying agents.

Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. WO 02/060384 A2, in view of Nishioka et al. US 5,861,173 or Gidwani et al. US 6,270,797 or Li et al. US 7,476,403.

Brown teaches an injection molded composition comprising 20-90% Eudragit 4135F, 0-10% surfactant, plasticizer, 0-10% processing aid, 0-30% lubricant such as stearyl alcohol, and 5-70% dissolution modifying agent such as HPC (pages 26-29, 34-36; and claims). The composition further comprises an absorption enhancer such as chitosan, lecithin, lectin, vitamin E, and mixture thereof (claims 23-24). The injection molded composition is suitable for the making of single capsule shell or multi-component capsule that comprises a plurality of sub-units (abstract; page 29, lines 29 through page 30, lines 1-6; and claims 39-42). The sub-units includes drug substances that can be the same or different (page 30, lines 16-37).

Brown does not explicitly teach mixture of at least two HPC having different MW. However, such combination is known in the art. See for example:

Nishioka at column 2, lines 25-50, for the teachings of combining HPC of different viscosity levels to obtain any release profile desired;

Gidwani teaches a sustained release composition comprising combination of HPC having different MW (column 3, lines 51-61; and example 4). Gidwani further

teaches the ratio between the at least two HPC with different MW is from about 1:6 to 6:1 (column 4, lines 1-7); and

Li teaches an oral extended release composition comprising mixture of at least two HPC having different MW (column 10, lines 47-59; Tables 8-10; and claims).

Thus, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to optimize the injection molding composition of Brown to include mixture of at least two HPC in view of the teachings of Nishioka, or Gidwani, or Li to obtain the claimed invention. This is because Nishioka teaches that selecting and combining at least two HPC of different viscosity levels, release profile of a dosage form can be adjusted; because Gidwani teaches that mixture of at least two HPC to obtain a sustained release profile is known in the art; because Li teaches that combining same polymers with different viscosity (V_1 and V_2), the release rate of the drug from the dosage form can be modified by adjusting the ratio of the polymers (column 8, lines 32-36); because Brown teaches that two or more polymers may be used in combination to form blends having the desired drug release profile (page 25, lines 24-26), and because Brown teaches the desirability for combining at least two dissolution (release) modifying agents (page 28; and claims 11-17).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615